

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC., INNOPHARMA
LICENSING, INC., INNOPHARMA LICENSING LLC, INNOPHARMA
INC., INNOPHARMA LLC, MYLAN PHARMACEUTICALS INC., and
MYLAN INC.

Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD.,

Patent Owner.

Case IPR2015-01105¹
Patent 8,871,813

**PATENT OWNER RESPONSE
PURSUANT TO 37 C.F.R. § 42.120**

¹ Case IPR2016-00090 has been joined with this proceeding.

Table of Contents

I.	Preliminary Statement	1
II.	Claim construction	6
III.	Level of ordinary skill in the art	7
IV.	The '813 patent	7
V.	Background of ophthalmic formulations	8
VI.	The combination of Ogawa and Sallmann, in either direction, does not render any claim of the '813 patent obvious	8
A.	No reason to focus on Ogawa and bromfenac preparations	8
B.	Design need and market demands would not have led a POSA in the direction that the inventors of the '813 patent took	10
C.	A POSA would not have combined Ogawa and Sallmann	14
	1. Ogawa and the problem it sought to solve	14
	2. Sallmann's singular purpose does not align with Ogawa's	17
	3. It would not have been obvious to modify Ogawa Example 6 in view of Sallmann Example 2	18
	4. Lupin's arguments of motivation and expectation of success ring hollow	25
D.	Sallmann in view of Ogawa: another hindsight-laden combination	29
	1. The proposed combination destroys the essential purpose of Sallmann and ignores the blaze marks in the art	30
	2. Lupin's arguments to modify Sallmann in view of Ogawa are legally insufficient, internally inconsistent, and belied by the very art Lupin cites	33

VII.	Compelling objective evidence of patentability	36
A.	Tyloxapol's unexpectedly superior chemical stabilizing effect	36
1.	Testing against the closest prior art	36
2.	A POSA's expectation, if anything, of polysorbate 80	38
3.	Tyloxapol's unexpectedly superior stabilizing effect	40
4.	Tyloxapol's unexpectedly better maintenance of preservative efficacy	45
B.	Additional compelling objective evidence of patentability	47
VIII.	Separate patentability of individual claims	52
A.	Separate patentability of claims 4, 6, 12, 16, 18 and 21-22	52
B.	Separate patentability of claims 7-12 and 19-22	56
IX.	Conclusion	59

TABLE OF AUTHORITIES

	Page(s)
Federal Cases	
<i>Allergan v. Sandoz</i> , 796 F.3d 1293 (Fed. Cir. 2015)	passim
<i>In re Antonie</i> , 559 F.2d 618 (C.C.P.A. 1977)	53, 56
<i>Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.</i> , 776 F.2d 281 (Fed. Cir. 1985)	58
<i>Atlas Powder Co. v. E.I. du Pont De Nemours & Co.</i> , 750 F.2d 1569 (Fed. Cir. 1984)	32
<i>Cadence Pharm. Inc. v. Exela PharmSci Inc.</i> , 780 F.3d 1364 (Fed. Cir. 2015)	passim
<i>Catalina Lighting, Inc. v. Lamps Plus, Inc.</i> , 295 F.3d 1277 (Fed. Cir. 2002)	36
<i>Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.</i> , 567 F.3d 1314 (Fed. Cir. 2009)	11, 12, 27, 32
<i>Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.</i> , 533 F.3d 1353, (Fed. Cir. 2008)	20, 21
<i>Galderma Labs. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013)	55
<i>In re Gordon</i> , 733 F.2d 900 (Fed. Cir. 1984)	30
<i>In re Gurley</i> , 27 F.3d 551 (Fed. Cir. 1994)	14, 24
<i>In re Huai-Hung Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011)	44

Patent Owner Response, IPR2015-01105, U.S. Patent No. 8,871,813

<i>Insite Vision Inc., v. Sandoz, Inc.,</i> 783 F.3d 853 (Fed. Cir. 2015)	13, 31
<i>Institut Pasteur v. Focarino,</i> 738 F.3d 1337 (Fed. Cir. 2013)	52
<i>Janssen Pharm. NV v. Mylan Pharm., Inc.,</i> 456 F. Supp. 2d 644 (D.N.J. 2006), <i>aff'd per curiam</i> , 223 Fed. Appx. 999 (Fed. Cir. 2007).....	51
<i>KSR Int'l Co. v. Teleflex Inc.,</i> 550 U.S. 398 (2007).....	33
<i>Microsoft Corp. v. Proxyconn, Inc.,</i> 789 F.3d 1292 (Fed. Cir. 2015)	7
<i>Ortho-McNeil Pharm. Inc. v. Mylan Labs, Inc.,</i> 520 F.3d 1358 (Fed. Cir. 2008)	36
<i>In re Papesch,</i> 315 F.2d 381 (C.C.P.A. 1963).....	44
<i>Par Pharm, Inc. v. TWI Pharms., Inc.,</i> 773 F.3d 1186 (Fed. Cir. 2013)	57
<i>Pfizer Inc. v. Mylan Pharm. Inc.,</i> 2014 WL 5388100 (D. Del. 2014).....	23, 26, 31
<i>In re Shetty,</i> 566 F.2d 81 (C.C.P.A. 1977).....	57
<i>Specialty Composites v. Cabot Corp.,</i> 845 F.2d 981 (Fed. Cir. 1988)	51
<i>Syntex LLC v. Apotex Inc.,</i> 2006 U.S. Dist. Lexis 36089 (N.D. Cal. 2006), <i>aff'd</i> 221 Fed. Appx. 1002 (Fed. Cir. 2007).....	19, 24
<i>Unigene Labs., Inc. v. Apotex, Inc.,</i> 655 F.3d 1352 (Fed. Cir. 2011)	20, 21, 53

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.